Greatbatch Medical

510(k) Summary

DEC 19 2012

Submitter's Name/Address:	Greatbatch Medical 2300 Berkshire Lane North Minneapolis, MN 55441
Contact Person:	Denise Thompson Sr. Regulatory Affairs Specialist Tel: 763-951-8254 Fax: 716-759-5040 dthompson@greatbatchmedical.com
Date Prepared:	September 14th, 2012
Trade Name:	MobiCath™ Transseptal Needle
Common Name:	Transseptal Needle
Classification Name:	Trocar
Product Code:	DRC
Regulation:	Class II 21 CFR 870.1390
Classification Panel:	Cardiovascular
Predicate Device:	MobiCath™ Transseptal Needle (*K111644*)

Device Description:
The MobiCath Transseptal Needles consist of a thin-walled stainless steel cannula bonded to an ergonomic handle and stopcock, and a removable stylet. The cannula is curved in the distal section to facilitate positioning in the cardiac anatomy when used in conjunction with an introducer or catheter. The handle is integrated with a pointer to show the orientation of the curve. The two-way stopcock facilitates air aspiration, fluid infusion, blood sampling, and pressure monitoring. The stylet attaches to the proximal end of the needle assembly.

Intended Use:
The MobiCath Transseptal Needles are used to create the primary puncture in the inter-atrial septum to facilitate the passing of an introducer or catheter through the septum from the right side of the heart to the left side.

Comparison to Predicate Device:
Greatbatch Medical proposes using an alternate stopcock for the MobiCath Trasseptal Needles. The current stopcock has been discontinued by the supplier. A similar stopcock has been tested as a replacement. A few minor design changes are required for the stopcock to interface with the handle components. In addition, a few manufacturing improvements have been proposed.

2300 Berkshire Lane North
Minneapolis, MN 55441
Main 763-951-8181
Fax 763-559-0148

The Intended Use and Indications for Use for the MobiCath Transseptal Needles have not changed.

The fundamental scientific technology of the MobiCath Transseptal Needles has not changed. The proposed modifications do not change the needle cannula or stylet, or the manner in which the needle punctures the inter-atrial septum.

The surgical approach and procedure have not changed.

The device use environment has not changed. The device is still intended to be used under prescription use by trained physicians in a surgical setting.

The overall device design has not changed. The device still consists of a cannula, handle, stopcock and stylet and these components continue to interact in the same manner. The proposed device changes only impact the dimensions and the material formulations of the stopcock and interfacing handle components.

Summary of Testing:
The following non-clinical tests were performed for the design changes to the MobiCath Transseptal Needle:

- Design Verification – Bench:
  - Visual & Dimensional Inspection
  - Functional Testing
  - Tensile
  - Torque
  - Stopcock gauging
  - Air and liquid leakage
  - Stopcock separation force
  - Stopcock resistance to override
  - Stopcock ease of assembly
  - Stopcock stress cracking
  - Stylet to stopcock retention force
  - Stylet insertion through needle
- Biocompatibility Testing
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity
  - Acute Systemic Injection
  - Materials Mediated Rabbit Pyrogenicity
  - Hemocompatibility
  - Hemolysis
  - Partial Thromboplastin Time
  - Platelet and Leukocyte Counts
  - Complement Activation – C3a and SC 5b-9
- Package Distribution Testing
- Shelf Life

- Sterilization Rationale
- EtO Residual Testing

Conclusion:
Failure Modes and Effect Analysis was used to identify the performance parameters potentially affected by the design modifications. The risks were addressed through verification and validation activities. The results from these activities demonstrate that the risks have been mitigated and that no new safety or efficacy issues were raised.

Greatbatch Medical considers the modified device to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Greatbatch Medical
Attention: Denise Thompson
Sr. Regulatory Affairs Specialist
2300 Berkshire Lane North
Minneapolis, MN 55441

DEC 19 2012

Re: K122832
Trade/Device Name: MobiCath Transseptal Needle
Regulation Number: 21 CFR 870.1390
Regulation Name: Cardiovascular devices - Trocar
Regulatory Class: Class II
Product Code: DRC
Dated: November 20, 2012
Received: November 28, 2012

Dear Ms. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.4 Indications for Use Statement

510(k) Number (if known): K122832

Device Name: MobiCath Transseptal Needle

Indications For Use:

The MobiCath Transseptal Needle is used to create the primary puncture in the inter-atrial septum to facilitate the passing of an introducer or catheter through the septum from the right side of the heart to the left side.

Prescription Use___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122832

Page 1 of 1